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JC02 Rec'd PCT/PT: 27 APR 2005

| TRANSMITTAL LETTE  | ATTORNEY'S DOCKET NUMBER 00005.001260                  |                       |  |  |  |  |  |
|--|--|-----------------------|--|--|--|--|--|
| DESIGNATED/ELECT   | U.S. APPLICATION NOT (17 how), sec. 7 R.4 5)           |                       |  |  |  |  |  |
| CONCERNING A SUBMI   |  |                       |  |  |  |  |  |
| INTERNATIONAL APPLICATION NO.  | INTERNATIONAL FILING DATE                              | PRIORITY DATE CLAIMED |  |  |  |  |  |
| PCT/JP03/014022 TITLE OF INVENTION   | 31 October 2003  | November 2002         |  |  |  |  |  |
| PERORAL PREPARATION FOR PREVENTION OR TREATMENT OF ATOPIC DERMATITIS   |  |                       |  |  |  |  |  |
| APPLICANT(S) FOR DO/EO/US  APR 2 7 2005 L  |  |                       |  |  |  |  |  |
| Tomoya Takahashi and Asako Kobayashi   |  |                       |  |  |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/E), the following items and other information:  |  |                       |  |  |  |  |  |
| 1. X This is a FIRST submission of items concerning a submission under 35 U.S.C. 378 AUG.  |  |                       |  |  |  |  |  |
| 2. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.   |  |                       |  |  |  |  |  |
| 3. X This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. |  |                       |  |  |  |  |  |
| 4. X The US has been elected (Article 31).   |  |                       |  |  |  |  |  |
| 5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2))  |  |                       |  |  |  |  |  |
| a. is attached hereto (required only if not communicated by the International Bureau).   |  |                       |  |  |  |  |  |
| b. X has been communicated by the International Bureau.  |  |                       |  |  |  |  |  |
| c. is not required, as the application was filed in the United States Receiving Office (RO/US).  |  |                       |  |  |  |  |  |
| 6. X An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).  |  |                       |  |  |  |  |  |
| a. X is attached hereto.   |  | ·                     |  |  |  |  |  |
| b. has been previously submitted under 35 U.S.C. 154(d)(4).  |  |                       |  |  |  |  |  |
| 7. X Amendments to the claims of the Inte  | rnational Application under PCT Article 19 (35 U.S.    | C. 371(c)(3))         |  |  |  |  |  |
| a. are attached hereto (required only if not communicated by the International Bureau).  |  |                       |  |  |  |  |  |
| b. have been communicated by   | the International Bureau.                              | ·   1                 |  |  |  |  |  |
| c. have not been made; however, the time limit for making such amendments has NOT expired.   |  |                       |  |  |  |  |  |
| d. X have not been made and will not be made.  |  |                       |  |  |  |  |  |
| 8. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |  |                       |  |  |  |  |  |
| 9. X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).  |  |                       |  |  |  |  |  |
| 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C.                                 |  |                       |  |  |  |  |  |
| 371(c)(5)).  |  |                       |  |  |  |  |  |
| Items 11 to 20 below concern other documen   | it(s) or information included:                         |                       |  |  |  |  |  |
| 11. An Information Disclosure Statement  | under 37 CFR 1.97 and 1.98.                            |                       |  |  |  |  |  |
| 12. X An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.  |  |                       |  |  |  |  |  |
| 13. X A preliminary amendment.   |  |                       |  |  |  |  |  |
| 14. X An Application Data Sheet under 37   | CFR 1.76.  |                       |  |  |  |  |  |
| 15. A substitute specification.  | :  | •                     |  |  |  |  |  |
| 16. A power of attorney and/or change of address letter.   |  |                       |  |  |  |  |  |
| 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.   |  |                       |  |  |  |  |  |
| 8. A second copy of the published International Application under 35 U.S.C. 154(d)(4) (cover only).  |  |                       |  |  |  |  |  |
| 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).  |  |                       |  |  |  |  |  |
|  | on of Translation; Form PCT/RO/101; Form PCT/IB/301; F |                       |  |  |  |  |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## JC13 Rec'd PCI/PIO 4 ( APK ZUU)

PTO-1390 (Rev. 02-2005)

Approved for use through 3/31/2007, OMB 0651-0021

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| U.S. APPLICATION NO (IEL-  | U.S. APPLICATION NO. (If thown, see 37 C.F.R.L.5)  INTERNATIONAL APPLICATION NO.  PCT//P03/014022 |   | ATTORNEY'S DOCKET NUMBER<br>00005.001260 |          |   |  |
|--|---|---|--|----------|---|--|
| The following fees are submitted:  |   | CALCULATIONS  | PTO USE ONLY                             |          |   |  |
| 21. X Basic national fee   |   |   | \$300.00                                 |          |   |  |
| 22. X Examination fee  If International preliminary examination report prepared by USPTO and all claims satisfy provision of PCT Article 33(1)-(4)   |   |   | \$200.00                                 |          |   |  |
| 23. X Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority   |   |   | \$400.00                                 | ·        |   |  |
| TOTAL OF 21, 22 and 23 =   |   |   | \$900.00                                 |          |   |  |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |   |   |  |          |   |  |
| Total Sheets   | Extra sheets  | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE                                     |          |   |  |
| 29 - 100 =   | /50 =   | 0   | x \$250.00                               | \$0.00   |   |  |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).   |   |   | \$                                       |          |   |  |
| CLAIMS   | NUMBER FILED  | NUMBER EXTRA  | RATE                                     |          | 1 |  |
| Total Claims   | 20 - 20 =   | 0   | x \$ 50                                  | \$0.00   |   |  |
| Independent Claims   | 5 - 3 =   | 2   | x \$200                                  | \$400.00 |   |  |
| MULTIPLE DEPEND  | DENT CLAIM(S) (if app   | plicable)   | + \$360                                  | \$360.00 |   |  |
| TOTAL OF ABOVE CALCULATIONS =  |   |   | \$1660.00                                |          |   |  |
| Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  |   |   | \$                                       |          |   |  |
| SUBTOTAL =   |   |   | \$1660.00                                |          |   |  |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority dte (37 CFR 1.492(i)).   |   |   | \$                                       |          |   |  |
| TOTAL NATIONAL FEE =   |   |   | \$1660.00                                |          |   |  |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +   |   |   | \$40.00                                  |          |   |  |
| TOTAL FEES ENCLOSED =  |   |   | \$1700.00                                |          |   |  |
|  |   |   | Amount to be refunded:                   | s        |   |  |
|  |   |   | Amount to be charged:                    | s        |   |  |
| a. X A check in the amount of \$1700.00 to cover the above fees is enclosed.   |   |   |  |          |   |  |
| b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.  |   |   |  |          |   |  |
| c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1205. A duplicate copy of this sheet is enclosed.  |   |   |  |          |   |  |
| d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.                       |   |   |  |          |   |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed   |   |   |  |          |   |  |
| and granted to restore the International Application to pending status.  |   |   |  |          |   |  |
| SEND ALL CORRESPONDENCE TO:  Lawrence S. Perry  SIGNATURE  |   |   | aoue X                                   |          |   |  |
| Fitzpatrick, Cella, Harper & Scinto  Lawrence S. Perr  |   |   |  |          |   |  |
| 30 Rockefeller Plaza NAME  |   |   |  |          |   |  |
| New York, NY 10112-3800 31,865   |   | April 26, 2005  |  |          |   |  |
| REGISTRATI   |   |   | ON NUMBER                                | DATE     |   |  |

10/532721 JC13 Rec'd PCT/PTO 27 APR 2005

## **VERIFICATION OF A TRANSLATION**

I, the below named translator, hereby declare that:

My name and post office address are as stated below:

That I am knowledgeable in the English language and in the language in which the below identified international application was filed, and that I believe the English translation of the international application No. PCT/JP2003/14022 is a true and complete translation of the above identified international application as filed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: April 8, 2005

Full name of the translator

Kazuyo Saito

Signature of the translator

Post Office Address

c/o Head Office, KYOWA HAKKO KOGYO CO., LTD.

1.6.1, Ohtemachi, Chiyoda ku, Tokyo 100-8185 Japan